

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/290,798	04/13/99	HELLSTROM	I 30436.33USC1

HM12/1106
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EXAMINER

BANSAL, G

ART UNIT PAPER NUMBER

1642

18

DATE MAILED: 11/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/290,798

Applicant(s)

Hellsbrom et al

Examiner

Lpetha Bansal

Group Art Unit

1642

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 8/13/01

☒ This action is FINAL.

- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 59-65, 71, 84, 93 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 59-65, 71, 84, 93 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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DETAILED ACTION

1. Applicant's remarks filed August 13, 2001 (Paper No: 14)) is acknowledged. Accordingly, claims have not been amended. Claims 59-65, 71, 86, 93 are still pending, and are being examined.

Response to Arguments

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Rejection of claims 59-65, 71, 86, 93 are rejected under 35 U.S.C. 103 (a) as being unpatentable over the combination of Abe et al, Kim et al and Hellstrom et al in view of Oldham et al and Schlom et al (Examiner apologizes for the inadvertent error in not including the secondary references in the statement of the rejection and including it only in the body of the rejection). Applicant argues that a prima facie case of obviousness has not been advanced, and that the combination of references fail to teach or suggest the present claims in that they fail to describe or suggest an immunoconjugate that comprises a Lewis Y specific antibody that is internalized by a carcinoma cell with which it reacts. Applicant argues that one of ordinary skill in the art would not have been motivated to make an internalizing antibody with a reasonable expectation of success. It is submitted that Schlom teaches the rationale for monoclonal antibody directed therapeutic and diagnostic applications, as well as the desirability of having the antigen antibody complex be internalized (see Table 6.2 of Schlom et al). Schlom also suggests that it would have been desirable to produce monoclonal antibody conjugates that would be able to internalize the cytotoxic activity (page 107, column 2 section headed "Drug and Toxin mAb Conjugates"). Further, the motivation is provided in that Schlom discusses that since some of the antigens that are specific to tumor cell surface or are tumor specific membrane antigens are stable and that a subset of Mabs (those that do not internalize) would be ineffective against the targets. Thus the motivation to produce internalizing antibodies have been taught by Schlom. As for

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expectations of success, one of ordinary skill in the art would have known at the time of the claimed invention how to screen for ligands that internalized into cells- such methods were routine to one of ordinary skill and were applicable to the screening of internalizing antibodies. Applicant argues that Kim et al, Hellstrom et al and Abe et al are silent with respect to the internalization. It is submitted that one of ordinary skill in the art would first have been motivated to identify tumor specific antigens and produce Mabs against them and use such Mabs as targeting agents for delivering drugs, toxins, other therapeutic agents to the tumors. Internalizing antibodies are desirable in those instances where there would have been a necessity for introducing the cytotoxic, diagnostic or therapeutic agent to the interior of the cell. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, there is ample motivation and suggestion to produce an internalizing Lewis Y specific antibody and conjugating it to therapeutic agent as taught by the combination of references.

4. Rejection of claims under the obviousness-type double patenting is maintained as applicant has not provided the terminal disclaimer.

5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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7. A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than **SIX MONTHS** from the date of this final action.

8. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-3014.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Geetha P. Bansal whose telephone number is (703) 305-3955. The examiner can normally be reached on Mondays to Fridays and alternate Wednesdays from 7:00am to 4:30pm and alternate Fridays from 7:00am to 3:30pm. A message may be left on the examiner's voice mail service.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Anthony Caputa, can be reached on (703) 308- 3995.

11. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

October 25, 2001



GEETHA P. BANSAL
PRIMARY EXAMINER